

**A CLINICAL STUDY TO EVALUATE THE EFFICACY OF MADANPHALADI VATI IN THE MANAGEMENT OF STHOULYA W.S.R. TO OBESITY-A PILOT STUDY****\*Vd. Archana Pandurang Kashid**

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**ABSTRACT****Aim:** "To study the efficacy of Madanphaladvati in the management of Sthoulya w.s.r. Obesity."**Objective**

- To evaluate the efficacy of Madanphaladvati in the management of sthouly (Obesity).
- Conceptual study of Sthoulya in Ayurvedic texts and Obesity in modern medicine.

**Methodology:** In present study, Thirty obese subjects fulfilling the diagnostic criteria of sthoulya who visited OPD, IPD of D.Y. Patil Ayurvedic Hospital, Nerul, Navi Mumbai has been selected & administered orally Madanphaladi vati 3 gm two times a day before food with lukewarm water & minimal diet, exercise for two months, follow up was done one month interval. The sign and symptoms and the BMI level, waist hip ratio were observed before and after treatment. Lipid profile was done before and after treatment. **Conclusion:** A significant weight loss was observed. The result shows marked improvement of sign and symptoms along with decrease in BMI, lipid profile level & waist hip ratio. Though the subjects was given treatment for short term, the result was encouraging. Moreover, further study with large sample size & long duration is desirable to establish the treatment.**KEYWORDS:** Atisthoula, Obesity, Madanphaladi Vati, Lipid profile.**INTRODUCTION**

Obesity is a condition analogous to descriptions of an Ayurvedic clinical conditions called as "Sthoulya".

Sthoulya is explained as santharpanotthavyadhi in Ayurveda. Atisthoula is one among the ashtanindithapurushas.

Sthoulya is a condition wherein there will be ayatopachaya of shareera associated with the abnormal increase in medodhatu. Charaka Samhita gives one of the best definition of sthoulya as 'The increase of the medo and mamsadhatu causes the flabbiness and thus movement of abdomen, buttocks and breasts. This improperly formed medodhatu causes utsahahani in the individual; such person is called Atisthoula. In the western medical science, Sthoulya can be compared with Obesity; Obesity is the abnormal growth of the adipose tissue due to an enlargement of fat cell size or an increase in fat cell number or a combination of both.

The conventional concept of etiopathogenesis, prognosis and management of obesity is very similar and equally advanced to the medoroga/sthoulya of ayurveda, which was conceived in 1500BC by Acharya Charaka. Overweight or obesity is mostly found in people with Kapha type constitutions. Obesity occurs when fat builds

up in the adipose tissues. Diseases like coronary thrombosis, Diabetes (T2DM), Heart disease (CHD), Stroke, Hyper tension, cholesterol and some type of cancers are health risks associated with the sthoulya.

Rapid urbanization and stress, westernization in food and sedentary life style has made Indians to suffer from obesity. Obesity is more common in both developing and developed countries worldwide. Prestige of social drinking in society, improper food habits etc are also attracting and pushing people into scales of overweight and obese category. Obesity is a complex multifactorial chronic disease developing from interactive influence of numerous factors like social, behavioural, psychological, cellular &amp; genetic factors. It is widely regarded as pandemic with potentially disastrous consequences for human health.

The Ayurvedic approach is perfect answer to overweight because ayurveda does not recommend weight losing pills or fast weight loss programs. In the field of Ayurveda it is experienced that 'Shodhan Chikitsa' is effective in Sthoulyavyadhi. While considering day-to-day life and available time factor of patient, 'Shaman Chikitsa' is preferable. Ayurveda has laid emphasis on the holistic solutions that allows the people to loose

excess weight and keep it off by specific dietary measures and life style measures.

### NEED FOR STUDY

Before the 20<sup>th</sup> century, obesity was rare; in 1997 the WHO formally recognized obesity as global epidemic. Once it was considered as problem only of high income group but recently its rates are rising worldwide and affecting both developed and developing world. These increases have been felt most dramatically in urban settings. As obesity is major risk factor for many diseases like diabetes, cardiovascular diseases, cancers etc; it has been seen that with the dietary regime, various life style measures should be not controlled effectively.

In the recent years, India is under siege. Junk food, alcohol and sedentary life style are leading us to silent self destruction, making one in every five Indian men and women either obese or overweight. Its prevalence has increased three fold between 1975 and 2016 and continues to rise. According to WHO estimation in 2016, more than 1.9 billion adults are overweight, of these over 650 million were obese. These include 12.6% women and 9.3% men in India. Prevalence of obesity is more in women when compared with men.

India saw significant rise in obesity from its 19<sup>th</sup> position for both men and women in 1975 to rankings 5<sup>th</sup> and 3<sup>rd</sup> respectively in 2016 reflecting increasing obesity trend amongst women worldwide. No wonder that the world health organization has concluded that obesity is the major unmet public health problem worldwide. Obesity is health hazard and detriment to well-being which is reflected in the increased mortality.

To be more specific in the geographical area, study reveals that 74% of the adolescents living in Navi Mumbai had a normal body mass index (BMI)-for-age, 17.4% are overweight while 8.5% are obese. The study concluded that the level of overweight and obesity increase with an increase in age and grade.

Being developing country with rising growth, Battle of efficient earning with time is fought at every step and every day. In most of the case either time for people from high income group or money for lower income group forces to restrict from first line of treatment which includes dietary measures and exercise. Viewing this, shaman chikitsa in ayurved is identified as preferable. Therefore, above research to study the efficacy of madanphaladichurna with limited adoption of first line of treatment in the form of moderate exercise and dietary measures is oriented to suite the people with reasonable time and money.

### AIM

“To study the efficacy of Madanphaladivati in the management of Sthoulya w.s.r. Obesity”.

### OBJECTIVE

- To evaluate the efficacy of Madanphaladivati (Trial Group) in the management of sthouly (Obesity).
- Conceptual study of Sthoulya in Ayurvedic texts and Obesity in modern medicine.

### MATERIALS AND METHODS

#### Materials

Madanphaladi Vati.

### DRUG REVIEW

#### Madanphaladi churna

madnaMi~fLamaustsaPtahairYTmastukma\\ È  
sapazargavaQaMpItmaitbaMRhNaraogajiat\ ÈÈ  
³ AYTAMgasaarsaMga`hsaU~ sqaana 24Å35’

According to Astangasangraha Sutra sthana 24/35, following drugs mixed in equal quantity used in churna form or in kwath form which destroys ati-sthulata. This kwath is also used for lepan purpose. Here, Vati form of the churna has used for this study.

**Table No. 1: Properties of the Drug under study viz. MADANPHALADI VATI are tabulated as below.**

Table No.	Latin Name	Guna	Rasa	Veerya	Vipaka	Doshagnata
Madanphala	Randiaspinosa.	Laghu, Ruksha	Kashaya, Madhur, Tikta, Katu.	Ushna	Katu	Kaphavatashamaka.
Haritki	Terminaliachebula.	Laghu, Ruksha	Kashaya, Tikta, Madhur, Katu, Amla	Ushna	Madhur	Tridoshashamak
Bibhitaki	Terminaliabelarica.	Ruksha, Laghu	Kshaya, Titkta, Madhur	Ushna	Madhur	Tridoshashamak Visheshtaha Kaphashamak
Amalaki	Emblicoefficialis.	Laghu, Ruksha	Amla, Kashaya, Madhur, Katu, Tikta	Sheet	Madhur	Tridoshashamak
Musta	Cyperusrotundus.	Laghu, Ruksha	Katu, Tikta, Kashaya.	Sheeta	Katu	PittaKaphashamak.
Saptaparna	Alstoniascholaris.	Laghu, Snighda	Tikta, Kashaya	Ushna	Katu	Kaphapittashamaka.
Nimba	Azadirachtaindica.	Laghu	Titkta, Kashaya	Sheet	Katu	Pitta-Kaphahara.
Kutaj	Holarrhenaantidysentrica	Laghu, Ruksha	Tikta, Kashaya	Sheeta	Katu	Pittakaphaharaka.
Patha	Cissampelospaireira.	Laghu, Tikshna.	Tikta	Ushna	Katu	Tridoshashamak
Aragwadha	Cassia fistula.	Guru, Mrudu, Snighda.	Madhura	Sheeta	Madhura	Tridoshashamaka.

Drug Authentication & standerdization were done by Quality control laboratory of the pharmacy.

**METHODS****Source of data****Study Site**

The subjects of either sex diagnosed to be suffering from sthoulya were selected from the OPD, IPD of Kayachikitsa Department & Special camps conducted in

of Dr. D.Y. Patil College Of Ayurveda, Research Institute and Hospital, Nerul, Navi Mumbai.

**Study Type** – Pilot study.

**Study design:** Single arm, openlabelled, prospective clinical study.

**Table No. 2: Interventions.**

Study Drug	Madanphaladi Vati
Dose	3gm BID
Time	Before Lunch. Before Dinner.
Route of Administration	Oral
Duration	2 Months
Assessments	Initials 1st, 30th, 60th, followup on 90th day.
Anupan	Koshnajala.
Sample size	30

Common Pathya/Apathya Chart was given to all subjects such as to avoid bakery products, sweet and salty items, Fried food, prohibition on alcohol, Junk/Fast food etc. & Diwaswap (Day Sleep) along with required moderate exercise including, brisk walking and recommended yogaasanas.

**Inclusion Criteria**

- Subjects having signs and symptoms of Sthoulya explained in Ayurvedic Texts.
- Subjects from age group 18 – 60 years.
- Subjects of both genders.
- Subjects had BMI between 25-40.
- Subjects who was ready to give written informed consent.

**Exclusion Criteria**

- Subjects below age of 18 and above age of 60 years irrespective of all sex.
- Obese subjects suffering from endocrine disorders like diabetes mellitus, hypothyroidism, cardiovascular diseases, hemiplegia, associated with severe hypertension & from other such diseases in which the subjects cannot do his routine physical activities was excluded.
- Sthoulya with pregnancy & with other significant associated illness, subjects who had cortico-steroids, oral contraceptive pills were excluded.

**Criteria for Assessment**

Subjective and Objective parameters with defined gradation were assessed studied to observe effect on the subject.

**Subjective Parameters**

Changes in the subjective parameters (signs & symptoms) of Sthoulya were assessed by Gradation method.

**1. Atikshudha**

Grade 0 – Feeling of hunger after 6 hours.

Grade I – Feeling of hunger between 5 to 6 hours.

Grade II – Feeling of hunger 4 hours after meal.

Grade III – Irritable desire of hunger 3 to 4 hrs after meal.

Grade IV – Irritable desire of hunger within 3 hours after meal.

**2. Atisweda**

Grade 0 – Sweating after heavy work and fast movement in hot season.

Grade I – Profuse sweating after moderate work and movement.

Grade II – Sweating after little work and movement.

Grade III – Profuse sweating after little work and movement.

Grade IV – Sweating even at rest or in cold season.

**3. Atindra**

Grade 0 – Normal sleep 6-7 hrs. per day.

Grade I – Sleep upto 8 hrs. per day with angagaurava.

Grade II – Sleep upto 8 hrs. per day with angagaurava and jumbha.

Grade III – Sleep upto 10 hrs. per day with tandra.

Grade IV – Sleep more than 10 hrs. per day with tandra and klama.

**4. Sweda Durgandhi**

Grade 0 – Absence of bad smell.

Grade I – Occasional bad smell in the body goes after bathing.

Grade II – Persistent bad smell limited to close areas difficult to suppress with deodorants.

Grade III – Persistent bad smell felt from long distance & not suppressed by deodorants.

Grade IV – Persistent bad smell felt from long distance & even intolerable to the patient himself.

**5. Aalasya**

Grade 0 – No Alasya (doing work satisfactory & in time).

Grade I – Doing work satisfactory with late initiation.

Grade II – Doing work unsatisfactory with lot of mental pressure and late in time. Grade III – No starting any

work in his own responsibility doing little work very slowly.

Grade IV –Does not have any initiation and not wants to work even after pressure.

#### 6. Shramashwasa

Grade 0 – Dyspnoea after heavy work (movement) but relieved soon and up to tolerance.

Grade I – Dyspnoea after moderate work but relieved later and up to tolerance.

Grade II – Dyspnoea after little work but relieved later and up to tolerance.

Grade III –Dyspnoea after little work but relieved later and beyond tolerance.

Grade IV –Dyspnoea in resting condition.

#### 7. Atipipasa

Grade 0 – Normal thirst.

Grade I – Upto 1 litre excess intake of water.

Grade II – 1 to 2 litre excess intake of water.

Grade III –2 to 3 litre excess intake of water.

Grade IV –more than 3 litre intake of water.

#### 8. Angasad

Grade 0 – Absent.

Grade 1 – Present.

#### 9. Alpa Vyavaya

Grade 0–Unimpaired libido and sexual performance.

Grade I–Decrease in libido but can perform sexual act.

Grade II–Decrease in libido but can perform sexual act with difficulty.

Grade III–Loss of libido and cannot perform sexual act.

#### Objective Parameters

- i) Weight.
- ii) BMI.
- iii) Waist Hip Ratio.
- iv) Lipid Profile.

#### INVESTIGATIONS

##### Essential investigations

Lipid Profile (Sr Cholesterol, Serum HDL, SerumLDL, SerumVLDL and Serum Triglyceride.) was carried out before and after study.

##### Desirable investigations

- 1) Blood sugar(Fasting & post prandial)
- 2) Serum T<sub>3</sub>, T<sub>4</sub>, TS

Above test was carried out if necessary.

The patient was assessed before and after the treatment on above parameters.

#### STATISTICAL ANALYSIS

The scores of assessment criteria were analyzed statistically in the form of mean score B.T. (Before Treatment); A.T. (After Treatment); Difference of mean (B.T. - A.T); S.D. (Standard Deviation); S.E (Standard Error). Student's „t“ test was carried out. The results were

considered Significant or Insignificant depending upon the value of P.

The obtained results were interpreted as;

Insignificant P< 0.05

Significant P<0.01

Highly Significant P<0.001

#### OBSERVATION AND RESULTS

Among 30 patients of Sthaulya, 56.66% of patients belongs to Body Weight ranging from 81-90 Kg's, 16.66% belongs Body weight ranging from 71-80 Kg's, 10% of patients belongs to Body Weight ranging from 61-70 Kg's and 91-100 Kg's respectively, 6.66% belongs to Weight ranging from 100-110 Kg's. Among 30 patients of Sthaulya, 80% of patients belong to BMI ranging from 30- 35Kg/m<sup>2</sup>, 20% belongs BMI ranging from 35- 40 Kg/m<sup>2</sup> and none of the patients belongs to BMI category ranging above 40 Kg/m<sup>2</sup>. Details of the patient in the trial group according to the Body weight and BMI are shown in Table No.3.

The mean score of Alasya before the treatment was 1.050, which was reduced to 0.6500 after the treatment. There was 38.09% improvement. The statistical analysis shows that the result was statistically significant at p<0.0021.

The mean score of Atipipasa before the treatment was 1.100 which was reduced to 0.7500 after the treatment. There was 31.81% improvement. The statistical analysis shows that the result was statistically significant at P<0.0047.

Before the treatment the mean score 52.38% improvement. The statistical analysis shows that the result was Highly significant at p<0.0001. of Atinidra was 1.050 which was reduced to 0.5000 after the treatment.

The mean score of Atisweda before the treatment was 1.400 which was reduced to 0.8500 after the treatment. There was 39.28% improvement. The statistical analysis shows that the result was highly significant at p<0.0001.

The mean score before the treatment for the symptom Swedadurgandhi is 1.200 which was reduced to 0.8500 after the treatment. There was 29.16% improvement. The statistical analysis shows that the result was significant at p<0.0047.

The mean score before the treatment for Shramashwas is 1.200 which was reduced to 0.6000 after the treatment. There was 50% improvement. The statistical analysis shows that the result was highly significant at p<0.0001.

The mean score before the treatment for Angasada is 1.600 which was reduced to 0.8000 after the treatment. There was 50% improvement. The statistical analysis shows that the result was highly significant at p<0.0001.

Before the treatment the mean score of Alpavyavaya was 0.5000 which was improved to 0.1000 after the treatment. There was an improvement of 80%. The statistical analysis shows that the result was significant at  $p < 0.0021$ .

The mean score of Athikshudha before the treatment was 1.500 which was reduced to 1.100 after the treatment. There was an improvement of 26.66%. The statistical analysis shows that the result was significant at  $p < 0.0021$ . (Table 4).

The mean score of Waist circumference was 1.900 which was reduced to 1.550.18.42% improvement was there. The statistical analysis shows that the result was highly significant at  $p < 0.0047$ .

The mean score of Hips circumference was 1.950 which was reduced to 1.700 with an improvement of only 12.82% and the statistical analysis shows that the result was significant at  $p < 0.0210$ .

The mean score of Waist hip ratio before the treatment was 1.700 which was then improved to 1.150 with an improvement percentage of 32.35%. The statistical analysis shows that the result was significant at  $p < 0.0001$ . (Table 5).

The mean score before treatment for weight is 1.500 which was improved to 1.150 after the treatment with an improvement of 23.33%. The statistical analysis shows that the result was significant at  $p < 0.0047$ . (Table 6).

**Table No. 3: Distribution of patients according to Body weight and BMI.**

Sr.no.	Criteria	Range	Total N=30	Percentage%
1	Weight	61-70	3	10
		71-80	5	16.66
		81-90	17	56.66
		91-100	3	10
		100-110	2	6.66
2	BMI	30-35	24	80
		35-40.	06	20
		>40	0	0

**Table No. 4: Effect on symptoms.**

Sr.no.	Symptomes	Mean		%	SD	SE	"t"Value	"P"Value
		B.T	A.T					
1.	Atikshudha	1.500	1.100	26.66	0.5026	0.1124	3.559	<0.0021
2.	Atisweda	1.400	0.8500	39.28	0.5104	0.1141	4.819	<0.0001
3.	Atinidra	1.050	0.5000	52.38	0.5104	0.1141	4.819	<0.0001
4.	Swedadurgandhi	1.200	0.8500	29.16	0.4894	0.1094	3.199	<0.0047
5.	Alasya	1.050	0.6500	38.09	0.5026	0.1124	3.559	<0.0021
6.	Shramashwas	1.200	0.6000	50	0.5026	0.1124	5.339	<0.0001
7.	Atipipasa	1.100	0.7500	31.81	0.4894	0.1094	3.199	<0.0047
8.	Angasada	1.600	0.8000	50	0.5231	0.1170	6.839	<0.0001
9.	Alpavyavaya	0.5000	0.1000	80	0.5026	0.1124	3.559	<0.0021

**Table No. 5: Effect on body circumference.**

Sr.no.	Body circumference	Mean		%	SD	SE	"t"Value	"P"Value
		BT	AT					
1.	Waist	1.900	1.550	18.42	0.4894	0.1094	3.199	<0.0047
2.	Hips	1.950	1.700	12.42	0.4443	0.0993	2.517	<0.0210
3.	Waist hip ratio	1.700	1.150	32.35	0.5104	0.1141	4.819	<0.0001

**Table No. 6: Effect on weight.**

Symptomes	Mean		%	SD	SE	"t"Value	"P"Value
	BT	AT					
Weight	1.500	1.150	23.33	0.4894	0.1094	3.199	<0.0047

**Assesmentof total Effect of Theraphy**

The total effect of therapy was assessed taking in to consideration the total all improvement in signs & symptoms & was calculated by formula-

$$=(\text{total BT}-\text{total AT}) \times 100/\text{total BT}$$

Complete remission	100% relief in signs & symptoms
Marked improvement	75-99% relief in signs & symptoms
Moderate improvement	50-74% relief in signs & symptoms
Mild improvement	25-49% relief in signs & symptoms
Unchanged	No change in signs & symptoms(<25%)

**Overall effect of MadanphaladiVati in the management of Sthoulya (Obesity)**

CATEGORY	NO.OF PATIENTS	%
Complete remission	0	0%
Marked improvement	1	3.333%
Moderate improvement	18	60%
Mild improvement	11	36.667%
Unchanged	0	0

**DISCUSSION**

Due to sedentary life style, unwholesome food habits, lack of physical exercise, mental stress etc factors is responsibalfor Sthaulya so it is considered as a burning problem of today's era. It is the doorway to other major health complications. Sthaulya was referred to as Obesity in this context as the symptomatology. Sthaulya Sthoulya is explained as santharpanothavyadhiin Ayurveda. Atisthula is one among the ashtanindithapurushas. In day-to-day life and available time factor of patient, 'Shaman Chikitsa' is preferable. Ayurveda has laid emphasis on the holistic solutions that allows the people to loose excess weight and keep it off by specific dietary measures and life style measures.

The parameters such as Atinidra, Atisweda, Shramashwas, Angasada showed better result that is highly significant improvement. The Parameters Atikshudha, Swedadurgandhi, Alasya, Atipipasa, Alpavyavaya showed significant improvement. The Madanphaladi Vati showed highly significant improvement in Waist-Hip ratio. The significant improvement in weight reduction.

**Probable Mode of Action of Madanphaladi Vati**

- Madanphaladivati contains ten types of herbal drugs in which most of drug having laghu and rukshaguna, which helps to absorb liquid part of excess medadhatu, so it helps in reducing excess aapdhatu from body.
- Also most probable drugs having tikta, katu, kashay rasa which helps to reduces kaph dosh along with kled and vikrutmeda. That's why it has Deepan, Pachana, Shrotosodhanaand Lekhanaproperties. It corrects all three Agni specially Dhatwagnimandhyta and reduces the Ama and Abadha medadhatu deposition.so it helps to break the samprapti of sthoulyavyadhi.

**CONCLUSION**

On the basis of Observations, results achieved & through discussion, following points were concluded.

- Sthoulya is a predominant metabolicdisorder, which is described by Charaka in Asthaunindita Purusha.
- Sthoulya is a Dushyadominant Vyadhi.
- Prestige of social drinking in society, improper food habits etc are also attracting and pushing people into scales of overweight and obese category.
- Madanphaladi Vati shows significant results in biochemical parameters & symptoms of sthoulya.
- Ayurvedic textual preparations Madanphaladi Vati improves quality of life in the patients of Sthaulya
- Conceptual study of sthoulya and modren literature of obesity were thoroughly studied and concluded the efficacy of classical Ayurveda drug (Madanphaladi Vati) as reviewed in texts.
- Madanphaladi vati is an effective, safe and economical alternative for the management of obesity or Sthoulya.

Though the subjects was given treatment for short term, the result was encouraging. Moreover, further study with large sample size & long duration with better parameters is desirable to establish the treatment.

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